K093639

DEC - 3 2009

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date : October. 12. 2009

1. Company and Correspondent making the submission:

Name – HUVITZ Co., Ltd.
Address - 689-3, Geumjeong-dong, Gunpo-si, Gyeonggi-do, 435-862, Republic of Korea
Telephone - +82-31-428-9100
Fax - +82-31-477-8618
Contact – Chang-Soo, Lee / QA Manager
E-mail – cslee@huvitz.com

2. Device:

Trade/ proprietary name : Slit Lamp HS-5500, HS-7000, HS-7500
Common Name : Slit Lamp
Classification Name : AC-Powered Slitlamp Biomicroscope

3. Predicate Devices:

Manufacturer : Huvitz Co.,Ltd.
Device : HS-5000
510(k) Number : K073190 (Decision Date – Jan. 11. 2008)

4. Classifications Names & Citations:

21 CFR 886.1850, HJO – AC-Powered Slitlamp Biomicroscope, Class 2

5. Description:

5.1 General

A slit lamp biomicroscope is intended for use in eye examination of the anterior eye segment, form the cornea epithelium to the posterior capsule. It is used to aid in the diagnosis of diseases or trauma which affect the structural properties of the anterior eye segment.

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These devices are designed for use by ophthalmologists and optometrists (within the realms of their respective professions) for specific diagnostic procedures (bio-microscopic examination of the eye)

5.2 Operation method

- Let the patient sit down comfortable with his chin on the chin-rest and his forehead against the forehead-rest.
- Lift or lower the chin-rest by moving the handle so that the patient's eyes are in line with the notches on the chin-rest.
- Switch the instruments on, press the switch. You will see the warning light on
- Adjust the luminous intensity by moving the selector
- Frame and focus the eye to be examined by moving the lever

5.3 Operation Principles

The instrument is consist of a microscope, a swiveling illumination system providing a slit image and a power supply

- AC Power is converted to DC Power through the SMPS.
- DC Power is supplied to the Lamp Providing the light.
- Light is converted to the slit image through the aperture, filter etc.
- The slit image is illuminate the eye.
- Observe the eye through the microscope.

6. Indication for use:

The Slit Lamps HS-5500, HS-7000, HS-7500 are intended for use in eye examination of the anterior eye segment, form the cornea epithelium to the posterior capsule. It is used to aid in the diagnosis of diseases or trauma which affect the structural properties of the anterior eye segment.

7. Comparison with predicate device:

HUVITZ Co., Ltd. Believes that the Slit Lamp, HS-5500, HS-7000 and HS-7500 are substantially equivalent to Slit lamp HS-5000 of Huvitz.,Ltd.

8. Safety, EMC and Performance Data:

Electrical, mechanical, and environmental safety testing according to Standard IEC 60601-1 was performed by UL Inc. EMC testing was conducted by UL Inc. in

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accordance with Standard IEC 60601-1-2(2001). The devices meet all requirements and passed all tests.

9. Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification HUVITZ Co., Ltd. concludes that the Slit Lamp, HS-5500, HS-7000 and HS-7500 are safe, effective and substantially equivalent to predicate devices as described herein.

10. HUVITZ Co., Ltd. will update and include in this summary any other information deemed seasonably necessary by the FDA.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

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Huvitz Co., LTD
c/o Mr. Marc M. Mouser
Section Manager & FDA Office Coordinator
Program Reviewer
Underwriters Laboratories, Inc.
2600 NW Lake Road
Camas, Washington 98607

Re: K093639
Trade/Device Name: Huvitz Slit Lamp, Models HS-5500, HS-7000 and HS-7500
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-Powered Slit lamp Biomicroscope
Regulatory Class: II
Product Code: HJO
Dated: November 6, 2009
Received: November 24, 2009

Dear Mr. Mouser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Kesia Alexander for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name : Slit Lamp HS-5500, HS-7000, HS-7500

Indications for Use:

The Slit Lamps HS-5500, HS-7000, HS-7500 are intended for use in eye examination of the anterior eye segment, from the cornea epithelium to the posterior capsule. It is used to aid in the diagnosis of diseases or trauma which affect the structural properties of the anterior eye segment.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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